EXHIBIT 30

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

The Max Harry
Weil Institute
FOR CRITICAL CARE RESEARCH & INNOVATION

North Campus Research Complex
2800 Plymouth Road
Ann Arbor, MI, 48109
(734) 647-4751

Via Electronic Submission

The Honorable Katherine M. Hiner
Acting Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Re: *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276

To the International Trade Commission,

My name is Kevin Ward, MD and I am a Professor in the Departments of Emergency Medicine and Biomedical Engineering at the University of Michigan. I am also a Fellow of both the American College of Emergency Physicians and the American Academy of Emergency Medicine. Prior to joining the University of Michigan in 2012, I was Professor and Associate Chair of Emergency Medicine at Virginia Commonwealth University (VCU) were I also founded and directed the VCU Reanimation Engineering Science Center (VCURES). I write in response to the Commission's solicitations of comments regarding the public interest, and in support of the suggested remedial orders against Apple. For the reasons described below, in my opinion, the Apple Watches with pulse oximetry capabilities does not benefit public welfare, and certainly not in any manner that outweighs the public's interest in strong intellectual property rights.

My research interests span the field of critical illness and injury ranging from combat casualty care to the intensive care unit. I develop and leverage broad platform technologies capable of use throughout all echelons of care of the critically ill and injured as well as in all age groups including noninvasive monitors and predictive algorithms. My work has been funded by the NIH, Department of Defense, NSF, and industry. My passion is in creating programs which encourage true integration across the disciplines of medicine, engineering, data sciences, and entrepreneurship that accelerate discovery to true patient impact. I am the founder of and executive director of the Max Harry Weil Institute for Critical Care Research and Innovation which is the largest critical care research enterprise in the U.S. I also led the design and implementation of Michigan Medicine's Fast Forward Medical Innovation program and served as its inaugural Executive Director from 2013-2018. I am a serial innovator and entrepreneur in the field of emergency and critical care medicine and the recipient of Innovation and Commercialization awards from Virginia Commonwealth University, the University of Michigan Medical School, and the Department of Defense. I am a named inventor on numerous patents and have founded over 8 companies. Five of my inventions have resulted in FDA approved products.

In collaboration with the U.S. Army and its Joint Special Operations Training Medical Center, I developed and medically directed special training programs, which have been responsible for providing clinical training to over 1000 Special Operation Combat Medics. For this work, the

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Department of the Army and the Joint Special Operations Training Center awarded me a Certificate for Patriotic Civilian Service. I am also a Lieutenant Colonel in the U.S. Army Medical Corps and its 948th Forward Resuscitation Surgical Team deploying to Afghanistan in support of Operation Freedom's Sentinel and the 10th Special Forces Group (Airborne).

I have published over 200 peer-reviewed articles and book chapters. I am the recipient of the Society of Academic Emergency Medicine's Excellence in Research Award as well as the American College of Emergency Physicians Outstanding Contributions in Research Award. I serve on numerous editorial and review boards in the field of resuscitation, emergency and critical care medicine, and also serve on the executive committee for the Trauma Hemostasis and Oxygenation Research (THOR).

Transformative lifesaving technologies do not get to a patient's bedside by themselves. The process requires a deep understanding of physiology, intellectual property, regulatory challenges, the market, as well as numerous other areas. This work costs significant amounts of resources, including time and money. The way innovators are able to protect such investments and hopefully recoup the investment is through intellectual property rights. Without enforcing such rights, the investments in companies developing life altering technologies will lose all incentive, and the public health will be the victim. For that reason alone, I support the exclusion rights as being in the public interest.

I am also very concerned about the proliferation of "medical devices" like the Apple Watch with pulse oximetry. These are not "medical devices" as the FDA would use the term. Indeed, I understand only software associated with the ECG feature of certain Apple Watches is FDA cleared. Apple has not received FDA clearance for its pulse oximeter and based on data collected by Masimo, it is certainly not clear Apple would receive FDA clearance for its pulse oximeter.[1] Despite this, it is my belief that confusion abounds in that many patients and medical professionals believe or at least use devices such as the Apple Watch as if they are FDA approved.

Specifically, Masimo's White Paper comparing the Masimo W1 to the Series 7 Watch with pulse oximeter obtained an adjusted A_{RMS} that would not meet current FDA clearance requirements. The results show the Series 7's pulse oximeter should not be used by medical professionals or patients, particularly because continuous measurements of blood oxygen saturation in patients is typically required.

I have serious concerns regarding patients treating an Apple Watch pulse oximeter as a medical device when such use has not been cleared by the FDA. Patients typically rely on large household brand-name technical companies like Apple to provide products that are beneficial, and not simply contain novelty functionalities. Apple's advertising of these medical functionalities appears to be an attempt to mislead the public into purchasing the devices as if it were a medical

[1] https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A_Whitepaper_Masimo_W1_US_v4.pdf?v=1670952306 ("White Paper")

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aid. I was shocked to see a video for the Apple Watch with pulse oximetry (referred to blood oxygen saturation) as something important to patients in view of the COVID-19 pandemic.[2] Although using blood oxygen saturation is useful for a physician, that does not mean the Apple Watch is capable of providing meaningful data—in my view it is not the type of device patients or physicians should rely upon for any medical purpose.

Moreover, contrary to the representations made by Apple in its marketing, the Apple Watch is not something that patients worried about COVID-19 should be relying on especially when there are FDA approved alternatives available. The Apple watch does not provide continuous measurements, much less claim to have medical grade capabilities in the pulse oximetry feature. Thus, I believe Apple's insinuation in the video that its watch is capable of providing "an indication of how well [your cardiovascular system] is functioning and of your overall respiratory and cardiac health" endangers public health. These current parameters provided and advertised by Apple simply do not have the fidelity and accuracy required for medical decision making.

In summary, I believe Apple's pulse oximetry, combined with its sale and marketing of that feature, has potential to harm the public health. Apple should not be allowed to use the inventions of other innovators based on unsupported allegations that its products might help people achieve improved outcomes. The public's interest in strong intellectual property rights, which will dictate future investments in future live-saving technologies, far outweighs the public's need for these novelty devices.

Very Respectfully,

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[2] https://www.youtube.com/watch?v=YKQFaPRObp8 at 2:42-3:28.